

Fu

**UNITED STATES PATENT AND TRADEMARK OFFICE**

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,998	09/14/2000	Michael Berthon Jones	3869/10	8889

7590 09/16/2002

Gottlieb Rackman & Reisman P C
270 Madison Ave
New York, NY 10016

EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
----------	--------------

3761

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/661,998

Applicant(s)
Berthon-Jones

Examiner
Joseph Weiss

Art Unit
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 14, 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 & 3 6) ☐ Other:

Art Unit: 3761

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-4 set forth in there base claims a “respiratory phase” which is understood in the art to be “inspiration, expiration, intervening pause or post-expiration/pre-inspiration.” However applicant goes on to claim “the phase” in claims 11, 16, 27 & 32 and then setting forth that “the phase” is quantified by a fraction of a “revolution” and in claims 27 & 32 applicant sets forth “the phase” as being “inspiratory” or “expiratory” and then the phase being “X decimal of a revolution” however outside of tracking this same claim language in the written description, applicant’s written description is devoid of any disclosure of establishing or equating any range of revolution values to being indicative of a commonly understood in the art “respiratory phase.” Accordingly, this aspect of the invention is not described in the written description in such a way as to convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 3761

(By dint of the doctrine of claim differentiation where expressly using inspiration and expiration in claims 16 & 32 is indicative that applicant's usage of "respiratory phase" is not referring to "respiratory phase" in its commonly accepted art specific manner and but to mean decimals of revolutions and by reading the claims in light of the written description where by not disclosing to the level of one of ordinary skill in the art the correlations between these fractions of revolutions and the commonly accepted usage of the term "respiratory phase" applicant means some sort of calculation "phase" terminology.)

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 17-32 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: An airflow sensor, a signal indicative of such airflow and connectivity/communication between the effort sensor and the essential airflow sensor sensors to the processor to send the signals to the processor for subsequent evaluation.

6. Claims 1-16 & 33-36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The provision of the basic components necessary for

Art Unit: 3761

one to employing the method. (See claims 17 & 37 and the rejection of the immediately preceding paragraph.)

7. Claim 17 recites the limitation "the instantaneous respiratory phase" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

In regards to claims 1, 17, 33 & 37 and further claims 9 & 25, they are indefinite due to the recitation of "desired ventilation" because in the art ventilation encompasses a multitude of different values, parameters and characteristics by which ventilation can be quantified. Minus the possibility that applicant is quantifying ventilation by way of pressure which is expressly set forth in the claims, it is unknown, indeterminate and thus indefinite as to what applicant is referring to and attempting to quantify when applicant sets forth that a "desired ventilation" is to have a minimum and maximum value.

8. Claim 37 recites the limitation "the instantaneous respiratory phase" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

9. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "respiratory phase" in claims 1-40 are used by the claim to mean "some fraction of a revolution (of a flow generation device???)", while the accepted meaning is "inspiration, expiration, intervening pause or post-expiration/pre-inspiration."

Claim Rejections - 35 USC § 102

Art Unit: 3761

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-2, 9-10, 17-18, 25-26, 33-34 & 37-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Banner et al (US 6390091).

In regards to claims 1, 17, 33 & 37, Banner discloses an apparatus for providing synchronized ventilatory support to a patient comprising at least one sensor to generate a respiratory effort signal (100), a processor for analyzing both respiratory air flow and the effort signal (60/62) which is fully capable of and does determine the instantaneous respiratory phase of a patient and generates a desired pressure request signal as a function of said instant phase and a desired ventilation (see generally figs 3-7 and supporting text and & Figs 11-12 and supporting text) and a servo-controlled blower (20) to provide pressurized air to a patient in accordance with the pressure request signal.

Art Unit: 3761

In regards to claim 2, 18, 34 & 38, Banner discloses the use of an esophageal pressure effort sensor (100, see fig 10)

In regards to claim 9 & 25, Banner discloses delivering ventilation with a maximum and non-zero minimum value range (Col. 7 line 65 to the end of the col.).

In regards to claim 10 & 26, Banner discloses the calculation/generation of a desired pressure request signal, including an error value that is a function of a difference between calculated/sensed ventilation and desired to targeted ventilation. (See col. 5 lines 15-27)

In regards to claims 19-32 & 39-40, the processor of Banner is fully capable of evaluating fuzzy inference rules related to various signals that are indicative of different aspects and parameters of pressure and ventilation in order to operate and control the system in response to the pulmonary needs of a user.

In regards to claims 27 & 32, while being parallel to the indefinite claims 11 & 16 have been rejected purely based upon the fact that in interpreting the claims the language present in these apparatus claims that parallels the indefinite language of claims 11 & 16 does not positively recite any structure or function or intended result or use or purpose that bring in by implication any structure, but merely present rules that any processor could evaluate, accordingly they can be rejected because they are not positive recitations that further limit the invention.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3761

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 3-8, 11-16 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banner in view of Schmidt (US 6186142).

In regards to claims 3-8, 12-15, 35-36, Banner substantially discloses the instant application's claimed invention to include the utilization of standard rules/algorithms in an "if--then" format (see figs 3-7 & 11-12) for evaluating respiratory signals, but does not explicitly disclose utilizing Fuzzy logic to evaluate respiratory signals. However, Schmidt disclose such (See figs 3-4, note col. 12 line 50-col. 13 line 60, specifically col. 12 lines 52-55). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Schmidt and used them with the device of Banner. The suggestion/motivation for doing so would have been because standard algorithmic if --then formats are interchangeable with fuzzy logic algorithmic formats (See Schmidt col. 12 lines 52-55). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Art Unit: 3761

In regards to claims 11 & 16, the claims are indefinite to the point that it is not possible to examine the claims on the substantive merits and apply prior art to make a determination of patentability.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6152129, 5692497, 5660171, 5582163, 5390666, 5316010, 5316009, 5307795, 5161525, 4957107, 4520812, 3807396,

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Aaron Lewis, can be reached at telephone number (703) 308-0716. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



Ifwc133

September 11, 2002



DENNIS RUHL
PRIMARY EXAMINER